REMARKS

Claims 1-5 and 12-13 are presented for examination. Claim 8, which is withdrawn, has been amended to refer to Claim 1. The amendment is supported by the specification and claims as originally filed. Accordingly, no new matter has been added. In addition, upon allowance of the elected claims, rejoinder of withdrawn Claims 7-8 will be appropriate, and is respectfully requested. The following remarks are in response to the Office Action dated July 17, 2008.

Rejection of Claims 1-6, 12 and 13 under 35 U.S.C. § 102(e)

The Examiner rejected Claims 1-6, 12 and 13 under 35 U.S.C. § 102(e) as allegedly anticipated by Lovett (U.S. Patent No. 6,881,419, hereinafter "Lovett"). Specifically, the Examiner asserts that Lovett describes a composition wherein the composition includes all of the limitations of the rejected claims. Applicants disagree and maintain that the claims are clearly novel over the Lovett reference.

Anticipation under Section 102 can be found only if a reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner, 778 F.2d 775 (Fed. Cir. 1985).* More particularly, a finding of anticipation requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention. *Electro Med. Sys. S.A. v. Cooper Life Sciences, 34 F.3d 1048, 1052 (Fed. Cir. 1994).* "To anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim." *Brown v. 3M, 265 F.3d 1349 (Fed. Cir. 2001).* In addition, "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson, 424 F.2d 1382, 1385 (CCPA 1970).*

As stated in Applicants' response filed April 28, 2008, Lovett fails to disclose an oral composition or agent comprising a soy isoflavone aglycone in the genistein/daidzein weight ratio and in the proportion of total aglycone weight set forth in Claim 1. Claim 1 recites an oral composition for alveolar bone resorption inhibition and periodontal membrane loss inhibition, comprising a soy isoflavone aglycone, calcium and vitamin D3, "wherein the soy isoflavone aglycone is obtained from or in an extract from whole-grain soy; the genistein/daidzein weight ratio in the soy isoflavone aglycone is in the range of 1/1 to 1.5/1; and the proportion of the total weight of genistein and daidzein in the soy isoflavone aglycone is at least 90%." Lovett fails to disclose a composition comprising soy isoflavone aglycone in the genistein/daidzein ratios and proportions as defined in Claims 1, 2 or 3.

In the Office Action dated July 17, 2008, the Examiner refers to USDA-Iowa State University Database (USDA), alleging that soy fiber has 18.8 daidzein, 21.68 genistein and a total isoflavone content of 44.3 mg/100g edible portion. Thus, the Examiner concludes, Lovett inherently discloses the claimed limitations because the total weight of genistein and daidzein in the soy is inherently 91%. However, Applicants note that there is a mistake in the USDA reference cited by the Examiner. The total isoflavones for soy fiber should be 18.8 + 21.68 + 7.90 = 48.38 mg/100g edible portion. Thus, the total weight of genistein and daidzein in the aglycone mixture is actually 83.6%, not 91%. Accordingly, even in light of the cited reference, Lovett does not inherently meet the claim limitations, which recite in part that "the proportion of the total weight of genistein and daidzein in the soy isoflavone aglycone is at least 90%" (emphasis added).

Furthermore, the Examiner refers to USDA data from soy fiber. In contrast, claim 1 recites, in relevant part, "wherein the soy isoflavone is obtained from or in an extract from whole-grain soy" (emphasis added). Soy fiber is merely one component of whole soybeans. In support of this, Applicants enclose herewith a reference from the United Soybean Board (http://www.soyconnection.com/health_nutrition/pdf/Nutrients.pdf). According to the chart on page 1 of the reference, the nutrient profile of a whole soybean is protein (38%), oil (18%), moisture ash (14%), fiber (15%) and carbohydrate (15%). Thus, as shown by this reference, soy fiber is merely one component of soybeans, and distinct from whole-grain soy. Accordingly, Lovett does not inherently meet the claim limitations, which recite in part that the soy isoflavone is obtained from or in an extract from whole-grain soy.

For at least these reasons, Lovett fails to disclose all of the elements recited in independent Claims 1, 2 and 3. Since each of dependent Claims 4, 5, 12 and 13 depends directly on Claim 1, 2 or 3, Applicants submit that those claims are also not anticipated by Lovett.

In view of the foregoing amendment and remarks, Applicants respectfully request that the Examiner withdraw the rejection of Claims 1-6, 12 and 13 under 35 U.S.C. § 102(e).

Rejection of Claims 1-6, 12 and 13 under 35 U.S.C. § 102(e) or § 103(a)

The Examiner rejected Claims 1-6, 12 and 13 under 35 U.S.C. § 102(e) as allegedly anticipated by Lovett or in the alternative, under 35 U.S.C. § 103(a) as obvious over Lovett. Specifically, the Examiner asserts that Lovett describes a composition wherein the composition

includes all of the limitations of the rejected claims. In the alternative, the Examiner asserts that the claimed invention was at least prima facie obvious in the absence of evidence to the contrary. In particular, the Examiner asserts it would be obvious to adjust particular conventional working conditions, and characterizes such adjustment as "merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan." However, as discussed below, this characterization of the differences between the claimed invention and the Lovett reference is inaccurate.

As noted above, there is a mistake in the USDA-Iowa State University Database (USDA), such that the total weight of genistein and daidzein in the aglycone mixture is actually 84%, not 91%. Further, as noted above, the cited USDA data shows merely the data of soy fiber and not of whole-grain soybeans. Accordingly, even in light of the cited reference, Lovett does not inherently meet the claim limitations, which recite in part that "the proportion of the total weight of genistein and daidzein in the soy isoflavone aglycone is at least 90%" (emphasis added). Thus, neither Lovett nor any other disclosure would lead one of skill in the art to arrive at the genistein/daidzein ratios or proportions recited in the present claims.

Further, in the Office Action dated July 17, 2008, the Examiner stated that Applicants' comments concerning the two references were not well taken because the references (Franke et al. and Kudou et al.) are not of record in the case. These references were inadvertently omitted in Applicants' prior response, and are enclosed herewith. Accordingly, Applicants request consideration of the following remarks that were provided in Applicants' prior Response:

As discussed above, independent Claims 1, 2 and 3 are not anticipated by Lovett, at least because of the genistein/daidzein ratios and the proportions of genistein/daidzein recited in these claims. In particular, the ratio of genistein/daidzein as defined in the independent claims is significantly different from that of the natural soy isoflavones used by Lovett. Moreover, the proportion of the total weight of genistein and daidzein in natural soy isoflavone aglycone is far less than that of the presently claimed soy isoflavone. In support of this, Applicants enclose herewith two references:

Adrian A. Franke et al., Proceedings of the Society for Experimental Biology and Medicine, Vol. 217, 263-273 (1998).

Shigemitsu Kudou et al., Agricultural and Biological Chemistry, Vol. 55, No. 9, pp.2227-2233 (1991).

These references show that the abundance ratio of daidzein is higher than genistein in natural soy beans as well as in hypocotyls of soy beans and that the proportion of aglycon in total isoflavones is very small (*see* Table III of Franke et al. and Table IV of Kudou et al.). The data of these references are organized in the following table:

	Aglycon			Glycoside or its derivatives		Total isoflavones (C)	(A+B)/ C
	Daidzein (A)	Genistein (B)	A+B	Daidzin	Genistin		
Soybean	52	28	80	861	735	1789	0.04
Hypocotyl	1020	350	1370	7430	3670	21850	0.06

*The values are calculated in mg/kg.

As shown in the above table, the ratio of genistein/daidzein is 0.54:1 in natural soybean and 0.34:1 in hypocotyls; and the ratio of aglycon to total isoflavones is 4% in natural soybean and 6% in hypocotyls. This data shows that daidzein exists more than genistein in natural soy beans, and that there exists very little aglycon (genistein and daidzein) compared to total soy isoflavones in nature. In contrast, independent Claims 1, 2 and 3 recite that the genistein/daidzein weight ratio in the soy isoflavone aglycone is in the range of 1/1 to 1.5/1; and that the proportion of the total weight of genistein and daidzein in the soy isoflavone aglycone is at least 90%. Therefore, the composition of the soy bean extract of the present invention is very unique compared to that of natural soy bean.

Thus, contrary to the assertion of the Examiner, the recited ratios and proportions cannot simply be obtained by judicious selection and routine optimization. In light of the dramatic differences from natural soy bean content, one skilled in the art would have absolutely no reason to arrive at the genistein/daidzein ratios or proportions recited in the present claims. It is only with improper hindsight and Applicant's disclosure as a blueprint that the particular ratios recited in Claims 1, 2, and 3 would have been obvious. Even under the looser standard set forth in the recent *KSR* decision of the U.S. Supreme Court, this clearly does not support *prima facie* showing of obviousness.

In light of the foregoing, Applicants submit that Claims 1-6, 12 and 13 are not anticipated under 35 U.S.C. § 102(e) and are not obvious under 35 U.S.C. § 103(a). As such, Applicants respectfully request withdrawal of this rejection and allowance of the pending claims.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

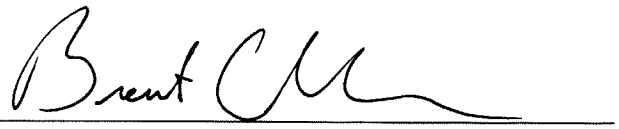
In view of the foregoing, Applicants respectfully request reconsideration of the outstanding rejections and, particularly, that all claims be allowed. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully invited to call the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 16, 2008

By: 

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